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10/823,778	04/14/2004	James Samsoundar	213202.00499	4689

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PATENT ADMINISTRATOR
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EXAMINER

SODERQUIST, ARLEN

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1797

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/823,778	Applicant(s) SAMSOONDAR, JAMES	
	Examiner Arlen Soderquist	Art Unit 1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-30 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 14 April 2004 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>10-14-04 and 5-8-07</u> . | 6) <input type="checkbox"/> Other: ____ |

1. The disclosure is objected to because of the following informalities: the continuing data found in paragraphs [0001] to [0004] needs to have the status of one or more applications updated, the application number of the application filed 3-22-04 is missing and the filing date of application 10/319,492 differs from that found in the USPTO records. If Application Serial Numbers are listed in other places in the specification (e.g. paragraph [0193]), the specification should be reviewed, the status of these applications should be checked and updated as appropriate.

Appropriate correction is required.

2. The incorporation of essential material in the specification by reference to an unpublished U.S. application, foreign application or patent, or to a publication is improper. Applicant is required to amend the disclosure to include the material incorporated by reference, if the material is relied upon to overcome any objection, rejection, or other requirement imposed by the Office. The amendment must be accompanied by a statement executed by the applicant, or a practitioner representing the applicant, stating that the material being inserted is the material previously incorporated by reference and that the amendment contains no new matter. 37 CFR 1.57(f).

3. The attempt to incorporate subject matter into this application by reference to one or more publications found in the specification (see paragraphs [0007], [0079], [0094], [0195] and [0242]) is ineffective because incorporation by reference of a publication is improper.

4. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the various sample vessels of claims 2, 12 and 22 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the

drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. With respect to the term aperture as used in the claims, paragraph [0116] has the following disclosure. "In the present example the attenuator is an aperture or channel (602) that can be of any appropriate diameter, but the channel could also be a fiber optic of any length or diameter, or other attenuating device, for example a filter or other device known to one of skill in the art that controls the amount of incident EMR reaching the sample slot (608)." Thus, the term aperture encompasses all of the above listed variations/equivalents.

6. Claims 2-3, 9, 12-13, 19, 22-23 and 29 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The independent claims do not have either the sample or the sample vessel positively recited as an element that limits the scope of the spectroscopic apparatus. Thus, claims which further define these things fail to further limit the scope of the parent claims.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 5 and 9-10 are rejected under 35 U.S.C. 102(b) as being anticipated by Rosse (US 3,703,336). In the patent Rosse teaches an analysis system employing a cuvette. Figure 1 shows slots (18-1 - 18-8) for inserting the cuvette assemblies (40). Figure 5 shows the cuvette assembly inside the slot and figure 7 shows the photometric system of the analyzer. These figures show a light source (90) and fiber optic channels (92, first aperture) extending therefrom to the slot and aligned fiber optic channels (94, second apertures) to receive the light and

transmit it to photosensors (96, photodiodes). The system has a card (42) with a data section (44) having control and calibration information. Column 8 has a table showing the various analyses that are capable of being run on the instrument including bilirubin. Column 5, line 8-12 teach that the data on the card identifies the particular test and had calibration information as a function of the test. Since this information is not determined on this analyzer the calibration information constitutes calibration information that primary calibration information that was developed on another instrument.

9. Claims 21-25 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Durley (US 5,075,077). In the patent Durley teaches an analysis system employing a test card (86) in a sample vessel (80). The figures show slots (98) on a carousel (18) for inserting the sample vessels. Figure 12 shows the photometric system of the analyzer. This figure shows a light source (LED 162) and a first aperture (166) extending therefrom to the sample vessel and second aperture (168) in the same side of the sample vessel to receive the reflected light and transmit it to a photodiode (164). The system has calibration data (300) provide as shown in figure 14 and its associated discussion in a machine readable format such as a barcode. Since this information is not determined on this analyzer the calibration information constitutes calibration information that primary calibration information that was developed on another instrument.

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jacobs (US 5,846,492) in view of Kowalski (US 5,459,677), Wehlburg, Greensill, Ozdemir (Applied Spectroscopy 1999), Sum, Despaigne or Swierenga. In the patent Jacobs teaches apparatus and method for detecting patient sample quality, and/or analytes, in the tip used to aspirate the patient sample liquid and then dispense it onto a slide test element. Spectrophotometric analysis is done on the liquid while still in the tip, by scanning the tip for transmittance in a light-tight enclosure, using NIR and adjacent visible radiation, and detecting the absorbance spectra of the liquid. Much smaller liquid volumes, and no through-the-label detection, are required, compared to doing the scanning of the liquid in a primary patient collection container. Figures 1-4 and 13-14 show various embodiments of an instrument having a slot for placing the sample vessel (a light-tight enclosure defining a cavity sized to receive the tip while mounted on the probe), a spectrophotometer emitting near infrared and adjacent visible radiation and generating a signal responsive to portions of the radiation absorbed by any medium the radiation passes through, passageways defining radiation paths to and from the enclosure from and to the spectrophotometer, the passageways being constructed to deliver and receive, respectively, the radiation for transmission through the tip when the tip is in place in the cavity, so that liquid in the tip can be irradiated by the radiation to determine concentration of target substances therein (see claim 1). Column 6, lines 3-10 teach as analytes at least hemoglobin, lipids, bilirubin (BR), and biliverdin (BV). Other compounds that are substances capable of spectrophotometric detection by its absorption spectra are also taught as possible analytes. The paragraph bridging columns 9-10 teaches a variety of calibration algorithms and derivatives used in the concentration calculations. Columns 10-11 give other examples of calibration algorithms used. Jacobs does not teach that the calibration algorithms were developed on another instrument and transferred to the instrument being used in the analysis.

In the patent Kowalski teaches calibration transfer for analytical instruments. In the background section Kowalski discusses calibration of analytical instruments and notes that calibration models are very powerful at deriving concentration information from spectra. However no two instruments are identical to each other. This creates the problem that the calibration model developed on one instrument cannot be used on another instrument without a

significant loss of accuracy. The ideal solution to this is to calibrate each individual instrument, but this is not practical and it would be highly useful to develop a technique to transfer a calibration model from a first or reference instrument to a second or target instrument. A technique for transferring a multivariate calibration model from a reference analytical instrument to a target analytical instrument that may be a different instrument, or the same instrument at a later time. In a "direct" approach, a plurality of transfer samples are selected, and a plurality of measurements are made for each transfer sample using the reference instrument, producing a reference instrument response for each sample. These measurements are repeated for the target instrument, to produce a target instrument response for each transfer sample. One then generates transfer coefficients capable of performing a multivariate estimation of the reference instrument responses for the transfer samples from the target instrument responses for those samples. The transfer coefficients may then be used to convert a target instrument response for an unknown sample into the equivalent response for the reference instrument. In an important "piecewise" variation, the transfer coefficients comprise a plurality of estimation coefficients for estimating each reference data value from more-than-one but less-than-all target data values. "Classical" and "inverse" transfer techniques are also described, wherein target instrument responses for the transfer samples are combined with reference instrument responses for the full set of calibration samples, to derive a multivariate prediction model for the target instrument.

In the paper Wehlburg teaches a new hybrid algorithm for transferring multivariate quantitative calibrations of intra-vendor near-infrared spectrometers. A new prediction-augmented classical least-squares/partial least-squares (PACLS/PLS) hybrid algorithm is ideally suited for use in transferring multivariate calibrations between spectrometers. Spectral variations such as instrument response differences can be explicitly incorporated into the algorithm through the use of subset sample spectra collected on both spectrometers. Two current calibration transfer methods, subset recalibration and piecewise direct standardization (PDS), also use subset sample spectra to facilitate transfer of calibration. The three methods were applied to the transfer of quantitative multivariate calibration models for near-IR (NIR) data of organic samples containing chlorobenzene, heptane, and toluene between a primary and three secondary spectrometers that were all the same model, called intra-vendor transfer of calibration. The

hybrid PACLS/PLS method outperformed subset recalibration and provided predictions equivalent to PDS with additive background correction on the two secondary spectrometers whose instrument drift appeared to be dominated by simple linear baseline variations. One of the secondary spectrometers had complex instrument drift that was captured by repeatedly measuring the spectrum of a single repeat sample. In calculating a transfer function to correct prediction spectra, PDs assumes no instrumental drift on the secondary spectrometer. Therefore, PDS was unable to directly accommodate both the subset samples and the use of a single repeat sample to transfer and maintain a calibration on that secondary instrument. In order to implement the transfer of calibration with PDS in the presence of complex instrument drift, recalibrated PLS models that included the repeat spectra from the secondary spectrometer were used to predict the spectra transformed by PDS. The importance of correcting for drift on the secondary spectrometer during calibration transfer was illustrated by the improvements in prediction for all three methods vs. using only the instrument response differences derived from the subset sample spectra. When the effects of instrument drift were complex on the secondary spectrometer, the PACLS/PLS hybrid algorithm outperformed both PDs and subset recalibration. Through the explicit incorporation of spectral variations, due to instrument response differences and drift on the secondary spectrometer, the PACLS/PLS algorithm was successful at intra-vendor transfer of calibrations between NIR spectrometers.

In the paper Greensill teaches calibration transfer between PDA-based NIR spectrometers in the NIR assessment of melon soluble solids content. In near-IR (NIR) spectroscopy, the transfer of predictive models between Fourier transform near-IR (FT-NIR) and scanning-grating-based instruments has been accomplished on relatively dry samples (<10% water) using various chemometric techniques-for example, slope and bias correction (SBC), direct standardization (DS), piecewise direct standardization (PDS), orthogonal signal correction (OSC), finite impulse transform (FIR) and wavelet transform (WT), and application of neural networks. In this study, seven well-known techniques [SBC, DS, PDS, double-window PDS (DWPDS), OSC, FIR, and WT], a photometric response correction and wavelength interpolative method, and a model updating method were assessed in terms of root mean square error of prediction (RMSEP) (using Fearn's significance testing) for calibration transfer (standardization) between pairs of

spectrometers from a group of four spectrometers for noninvasive prediction of soluble solid content (SSC) of melon fruit. The spectrometers were diffraction grating-based instruments incorporating photodiode array photodetectors (MMS1, Carl Zeiss, Jena, Germany), used with a standard optical geometry of sample, light source, and spectrometer. A modified WT method performed significantly better than all other standardization methods and on a par with model updating.

In the paper Ozdemir teaches multi-instrument calibration with genetic regression in UV-visible spectroscopy. The applicability of genetic regression (GR) to multi-instrument calibration was demonstrated by using several UV-visible spectrophotometers. GR is a calibration technique that optimizes linear regression using a genetic algorithm (GA). Sample spectra of ternary and quaternary mixtures of the pharmaceuticals furaltadone (Fd), doxycycline (Dx), sulfadiazine (Sd), and trimethoprim (Tm) were collected on four different UV-visible spectrophotometers, including one single-beam diode array and three double-beam dispersive instruments. Hybrid calibration models (HCMs) were generated by combining the data collected on multiple instruments into one calibration model as if they had all been collected on a single instrument. For comparison, single-instrument calibration models were also generated for each instrument. Both HCMs and single-instrument models were tested by using a validation set measured on all four instruments. Results obtained from single-instrument models were comparable with a previous study in which partial least squares (PLS) regression was used for multivariate calibration of these compounds. HCMs for double-instrument cases performed equally well as single-instrument models and slightly worse for the four-instruments models.

In the paper Sum discusses standardization of fiber-optic probes for near-infrared multivariate calibrations. The standardization of Fourier transform near-IR (FT-NIR) spectrometers equipped with fiber-optic probes was studied. FT-NIR spectra of caustic brines for an industrial process were measured on two different instruments. Calibration transfer across the instruments and probes was studied by employing calibration models built on one instrument to predict properties from spectra measured on the other. The transfer was examined by using spectra without and with preprocessing. The preprocessing methods included a Savitzky-Golay (SG) derivative polynomial filter, a procedure based on a finite impulse response (FIR) filter, and

a combination of both. In addition to being a preprocessing technique, the FIR filter is also a standardization method that transforms the instrument response function of one instrument to match that of another. The transformation was performed over a moving processing window without the use of transfer standards. Application of the FIR filter to 1st-derivative spectra provided the best multivariate calibration models and led to the successful transfer of calibration across different probes and spectrometers.

In the paper Despagne teaches transfer of calibrations of near-infrared spectra using neural networks. A new approach for multivariate instrument standardization is presented. This approach is based on the use of neural networks (NNs) for modeling spectral differences between two instruments. In contrast to the piecewise direct standardization (PDS) method to which it is compared, the proposed method builds a single transfer model for all spectral windows. The apparently incompatible requirements for a high number of training objects and a low number of standardization samples are addressed by truncating spectra in finite-size windows and assessing a position index to each window. Each spectral window with the corresponding position index constitutes a training object. No prior background correction is required with this method. Both the proposed method and PDS were applied to some real and simulated data sets, and results were evaluated for reconstruction and subsequent calibration. On the studied data sets, the neural network approach was found to perform at least as well as PDS for both reconstruction and calibration.

In the paper Swierenga presents a comparison of two different approaches toward model transferability in NIR spectroscopy. Recently, efficient methods have become available to transfer a multivariate calibration model from one instrument to another. Two categories can be distinguished: improvement of the robustness of the calibration model by, for example, proper data preprocessing; and adaptation of the calibration model by, for example, (piecewise) direct standardization. In direct standardization, a subset from the calibration set should be measured on both instruments. Usually, however, the calibration samples cannot be measured on both instruments. When data preprocessing is applied to the transfer of multivariate calibration models, there is no need for remeasurement of a subset on both instruments. In this paper, both categories are compared for the determination of the component concentrations in a ternary

mixture of methanol, ethanol, and 1-propanol using NIR spectroscopy. The calibration models obtained on one instrument are transferred to other NIR instruments. It has been found that the results of proper data preprocessing are comparable with the results obtained by direct standardization when the models are transferred over three NIR instruments.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the calibration transfer methods of Kowalski, Wehlburg, Greensill, Ozdemir, Sum, Despagne or Swierenga to provide the calibration algorithms used by Jacobs from a primary or reference instrument because of the ability to overcome the problem of variance between instruments taught by at least Kowalski with accuracy that is similar to that that would have been obtained by performing the calibration on each instrument as taught by Kowalski, Wehlburg, Greensill, Ozdemir, Sum, Despagne or Swierenga.

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additionally cited art relates to calibration methods and their transfer between instruments.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arlen Soderquist whose telephone number is (571) 272-1265. The examiner can normally be reached on Monday-Thursday and Alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



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